STERILE WATER - water injection, solution
Hospira, Inc.

VisIV™ Container
FOR DRUG DILUENT USE ONLY
Flexible Plastic Container
R_x only

DESCRIPTION
Sterile Water for Injection, USP is a sterile, nonpyrogenic, solute-free preparation of distilled water for injection. It is for use only as a sterile solvent or diluent vehicle for drugs or solutions suitable for parenteral administration. The pH is 5.5 (5.0 to 7.0).
Sterile Water for Injection contains no bacteriostat, antimicrobial agent or added buffer and is intended only for single-dose injection after admixture with an appropriate solute or solution. When smaller amounts are required, the unused portion should be discarded.
Sterile Water for Injection is a pharmaceutic aid (vehicle) and parenteral fluid replenisher after addition of an appropriate solute.
Water for Injection, USP is chemically designated H_2O.
The flexible plastic container is fabricated from a clear multilayer plastic film. Exposure to temperatures above 25°C (77°F), during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY
When administered intravenously as a vehicle for drugs, sterile water for injection provides a source of water for parenteral fluid replenishment after sufficient solute is introduced to achieve an osmolarity of 112 mOsmol or more per liter.
Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).
Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE
Sterile Water for Injection, USP is indicated for use only as a solvent or diluent vehicle for parenterally administered drugs or solutions and as a source of water for parenteral fluid replenishment after suitable additives are introduced.
For intravenous administration, an osmolar concentration not less than two-fifths (0.4) of the normal osmolarity of the extracellular fluid (280 mOsmol/liter) is essential to avoid intravascular hemolysis.

CONTRAINDICATIONS
Do not administer without the addition of a solute.

WARNINGS
FOR DRUG DILUENT USE ONLY.
Intravenous administration of Sterile Water for Injection, USP without additives may result in hemolysis.
The intravenous administration of sterile water for injection with additives can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.
WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.
Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS
Do not use for intravenous injection unless the osmolar concentration of additives totals at least 112 mOsmol/liter (two-fifths of the normal osmolarity of the extracellular fluid — 280 mOsmol/liter).
Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Pregnancy Category C.
Animal reproduction studies have not been conducted with sterile water for injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile water for injection with additives should be given to a pregnant woman only if clearly needed.

Pediatric Use:
The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.
This product contains no more than 25 mcg/L of aluminum.

ADVERSE REACTIONS
Reactions which may occur because of the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE
In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS.

DOSAGE AND ADMINISTRATION
Following suitable admixture of prescribed additive, the dose is usually dependent upon the age, weight and clinical condition of the patient.

DRUG INTERACTIONS
Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED
Sterile Water for Injection, USP is supplied in a single-dose 1000 mL flexible plastic container (NDC 0409-7990-48).

INSTRUCTIONS FOR USE
Check for leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.
To Add Medication
(Use aseptic technique)
1. Remove blue cap from sterile medication additive port at bottom of container.

2. With a needle of appropriate length, puncture resealable additive port and inject. Withdraw needle after injecting medication.

3. Mix container thoroughly.

4. The additive port may be protected by an appropriate cover.

Preparation for Administration
(Use aseptic technique)
NOTE: See appropriate I.V. administration set Instructions for Use. Do not administer without the addition of a solute.
1. Close flow control of administration set.

2. Remove cap from sterile administration set port at bottom of container.

3. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.

4. Suspend container.

5. Squeeze and release drip chamber to establish proper fluid level in chamber.

6. Open clamp. Eliminate air from remainder of set.

7. Attach set to patient access device.

8. Begin infusion.

WARNING: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.
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